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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/367,950 08/18/99 EKSTROM

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EXAMINER

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ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/25/01

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/367,950

Applicant(s)

EKSTROM, TOMMY

Examiner

Jennifer M Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Prosecution Application

1. The request filed on August 21, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/367950 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 13-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling of record in view of Vanzielegghem et al. and Sykes et al.

Vanzielegghem teaches on the abstract that budesonide was used as needed bases up to four times per day to treat allergic rhinitis.

Sykes et al. teaches on the abstract that formoterol was used as a patient's approach in treating their asthma by taking an extra dose when needed to achieve a more realistic method of assessing duration of action of formoterol.

Sykes et al. also suggest on the abstract that for older asthmatics with a degree of fixed airflow obstruction, the doses of formoterol should be taken 8 hourly (3 times a day).

Carling teaches at page 8-14, page 3, line 35 through page 4, line 10, lines 30-35, page 6, lines 5-30, and page 7, lines 1-5, teach a composition comprising Applicant's active agents use for treating respiratory disorder such as asthma set forth in claims 13-15, 17-18, 20-21, and 23.

Carling et al. at page 4, lines 3-10, also teach that the combination of formoterol and budesonide has not only a greater efficiency and duration of bronchodilator action but a rapid onset of action.

The difference between Carling et al. and Applicant's invention is instructing a patient to inhale, on demand, as determined by the patient based on the patient's symptoms, to provide short-term symptomatic relief of asthma symptoms set forth in claim 13, a specific carrier set forth in claim 24, the molar ratio of active agents set forth in claim 14, specific epimer set forth in claims 16 and 19, and the particle size set forth in claim 22.

However, to instruct the patient to inhale, on demand, as determined by the patient's symptoms is obvious in view of Vanzieleghe et al. and Sykes et al. who teach that individual active agents can be used as needed bases for treatment of allergy related diseases. The skilled artist would have been motivated to instruct the patient to use the Carling's composition as needed bases since each of the active agents can be used as needed bases since one reference relates to the active agent, formoterol use as

Art Unit: 1617

needed bases for a patient's approach in treating their asthma by taking an extra dose when needed and other reference related second active agent also can be use as needed bases for allergy related disease. The skilled artisan would have been motivated to instruct the patient to use the composition comprising both active agent is safe to use as needed bases in treatment of asthma since it is routinely use as needed bases individually. The molar ratio of active agents to be used, the selection of carrier, and the particle size of active agents, and specific epimer are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations. It would have been obvious to skilled artisan to use well known, potent form of Formoterol such as (R,R)-Formoterol and 22R epimer of budesonide which is also well known to be potent than 22S epimer of budesonide in treatment of asthma.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Argument

Applicant's argument have been fully considered but they are not persuasive.

Applicant argue that as claimed, the frequency of inhalation is determined by the patient, based on the patient's symptoms, on other days the same patient would in all probably inhale the medication more or less frequently than twice a day. Applicant further argue that Carling provides no teaching or suggestion of the claimed patient-determined mode of administration instead twice a day regimen prescribed by the physician.

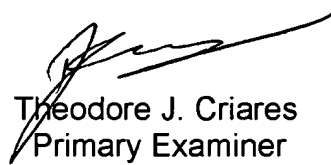
This is not persuasive since both of the references (Vanzielegthem et al. and Sykes et al.) teaches each of active agents can be use as as needed bases for treatment of allergy related diseases, these references teach that both of active agents were used as needed as it was determined by the patient, based on their symptoms. Therefore, the skilled artisan would have been motivated to instruct the patient that the Carling composition can be also use as needed bases since they are routinely used as needed bases individually when they needed depends on their symptoms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is (703) 308-2232. The examiner can normally be reached on Monday through Friday from 9 AM. to 4 PM.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
September 10, 2001